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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,060	01/14/2002	Anand Baichwal	540.1004CON2	3558

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AZPURU, CARLOS A

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1615

DATE MAILED: 09/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 10/047,060	Applicant(s) Baichwal et al
Examiner Carlos Azpuru	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Aug 20, 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-43 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-43 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other: _____

DETAILED ACTION

Receipt is acknowledged of the extension of time and amendment filed 08/20/02.

The following rejections are maintained in this action:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 26-43 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Device limitations critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

The disclosure lacks any enablement for a claimed device other than the basic output port, actuator and chamber. No other device limitations are found in the applications which would enable those of ordinary skill to make, use or practice the claimed device. Clarification is requested.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims lack any device limitations which would particularly point out the claimed invention. Applicant is attempting to limit the device through the use of a claimed composition only. The claims are therefore indefinite in that they do not distinctly claim a device.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Evans et al.

Evans et al disclose a device for delivering medicament to a patient comprising an output port, a chamber, and an actuator which propels the medicament through the output port (see Abstract; Figure 3; and claims). The method of treating a patient by inhalation is disclosed at col. 1, lines 1-18. Composition limitations can not be used to define the claimed device over that of the prior art. Further, the claims lack any device limitations. The instant claims sets out a device which is clearly anticipated by the Evans et al.

Claims 26-43 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Burns et al.

Burns et al disclose a device which comprises an output port, an actuator, and a chamber (see Figure 4A; col. 7, lines 40-62; and claims). The method of delivery is disclosed at col. 5, lines 47 et seq; and cols. 6-7. Composition limitations can not be used to define the claimed device over the prior art. Further, the claims lack any device limitations. The instant claims are clearly anticipated by Burns et al.

Response to Arguments

Applicant's arguments filed 08/20/02 have been fully considered but they are not persuasive.

Applicant argues that if the ordinary practitioner would be enabled to make, use or practice the claimed device in view of the devices incorporated by reference in the specification. However, review of those prior art references indicates that for the most part, inventions are directed to the compositions to be delivered, and not the devices claimed. In the case of US Patent No. 4,590,206 (which appears to be the only exception), aerosol containers are described. Therefore, it is unclear that the ordinary practitioner to gain any useful guidance in how to make, use or practice the invention. Certainly applicant is not describing an aerosol device. The instant rejection under 35 USC 112, first paragraph is therefore maintained.

Applicant argues that the independent claim recites a "device with an output port defining a passage, a chamber ...and an actuator. These appear to be the only device limitations set out by the applicant. How does the ordinary practitioner would be able to

define the invention by using the only device limitations of the claims. Applicant also argues that the claims are directed to a device with a particular formulation contained therein. However, applicant is reminded that the pharmaceutical formulation does not further limit the claimed device. Therefore, the rejection under 35 USC 112, second paragraph is maintained.

With regard to the rejection under 35 USC 102(b) over Burns et al, as well as Evans et al, applicant argues that the rejection is improper because the reference does not contain the particular xanthan gum and locust bean gum of instant claim 26. However, applicant is reminded that the instant claims are directed to a device, not a pharmaceutical. As such, the burns reference clearly sets out the only device limitations found in the instant claims. That is, Burns et al claim a device for delivering a medicament comprising an output port, a chamber, and an actuator. Therefore Burns et al does indeed set out each and every device limitation. The pharmaceutical does not determine the patentability of the device.

Applicant's argument as to this examiner's reasoning is not pertinent to this example because in that case the formulation (composition) is indeed defined by the novelty of the formulation, not the capsule. But again, applicant is using an example of a composition claim, not a device claim.

Further, while applicant recites the decisions in *Radio Steel & Mfg. Co v. MTD products, Inc*, 731 F.2d 840, (Fed. Cir. 1984) at 845, and *In re Bernhart*, 417 F. 2d. 1395, (1969) at 1403; and M.P.E.P. at 2173.05(j), it is noted that the improvement cited in

those cases was a further limitation of what was being claimed. In this application, applicant is seeking to further limit a device through the use of pharmaceutical limitations.

Referring to *In re Bernhart*, 417 F. 2d. 1395, (1969) at 1402, applicant is attempting to say that the composition in the device is an “improvement” over the prior art, although the only device limitations in the claims fail to improve any aspects in the prior art. As such, this case does not apply.

As noted by applicants, the composition itself is novel, and accordingly was granted a patent. However, applicant can not use that pharmaceutical to define a device claim. If applicant were claiming a device with any device limitation more than an actuator, chamber, and output port, which was novel in the art, the claims would be allowable. However, since applicant chose to only define the device through these three limitations, the prior art by Burns et al and Evans et al. clearly anticipate the instant claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

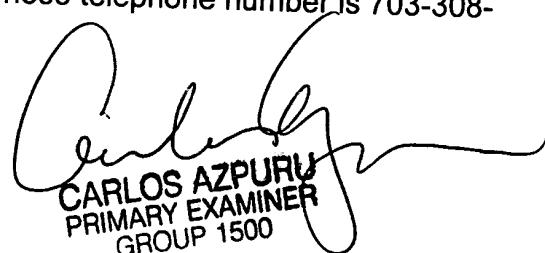
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is 703/308-0237. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

ca
September 25, 2002



CARLOS AZPURU
PRIMARY EXAMINER
GROUP 1500